

# **EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOVAIL LABORATORIES INTERNATIONAL SRL	)	
a corporation of Barbados,	)	
	)	
Plaintiff,	)	C.A. No. 05-586 (KAJ)
	)	
v.	)	
	)	
ANDRX PHARMACEUTICALS, LLC and	)	
ANDRX CORPORATION,	)	
	)	
Defendants.	)	

**BIOVAIL'S RESPONSES TO DEFENDANT  
ANDRX'S FIRST SET OF INTERROGATORIES**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and the Local Civil Rules of the United States District Court for the District of Delaware, Plaintiff Biovail Laboratories International SRL ("Biovail"), submits the following responses and objections to Defendants, Andrx Pharmaceuticals, LLC and Andrx Corporation (collectively "Andrx") First Set of Interrogatories to Biovail.

### **GENERAL OBJECTIONS**

Biovail makes the following General Objections to Andrx's First Set of Interrogatories, which apply to each individual Interrogatory, and shall have the same force and effect as if fully set forth in response to each individual Interrogatory.

1. Biovail objects to the Interrogatories to the extent that they seek information or concern persons that are not within the possession, custody or control of Biovail.
2. Biovail objects to the Interrogatories to the extent that they purport to impose obligations on Biovail that exceed its obligations under the Federal Rules of Civil Procedure and the Local Civil Rules of the United States District Court for the District of Delaware.
3. Biovail objects to the Interrogatories to the extent that they are vague, ambiguous, indefinite, overly broad, unduly burdensome, not reasonably calculated to lead to the discovery of admissible evidence, seek information that is irrelevant to any claim or defense in this action, and would require Biovail to conduct an unreasonable search for responsive information.
4. Biovail objects to the Interrogatories to the extent that they call for the disclosure of confidential information of any third party that is in Biovail's possession pursuant to confidentiality and non-disclosure restrictions imposed by contract or applicable law.
5. Biovail objects to the Interrogatories to the extent that they call for information with respect to facts occurring after June 22, 2005, the date of the first Notice pursuant to Title I of the Drug Price Competition and Patent Term Restoration Act of

1983, Section 505(j)(2)(B)(i) and (ii) concerning generic Cardizem LA, as overly broad, unduly burdensome, not reasonably calculated to lead to the discovery of admissible evidence, and seeking information that is irrelevant, privileged and subject to the work product doctrine.

6. To the extent Biovail responds to any of Andrx's Interrogatories, it does not concede that the information requested is relevant to this action. Biovail expressly reserves the right to object to further discovery into the subject matter of any of Andrx's Interrogatories, and the introduction into evidence of any information produced in response to Andrx's Interrogatories.

7. Biovail objects to these Interrogatories to the extent that the subject matter of the Interrogatories is more properly addressed by other forms of discovery, including, for example, through expert reports. Biovail further objects to these Interrogatories to the extent that they seek expert testimony.

8. Biovail objects to these Interrogatories to the extent that they call for a response to allegations or positions that are not articulated in Andrx's Answer, Affirmative Defenses and Counterclaims or Andrx's Paragraph IV Certification Notices, which is Biovail's only sources of information as to Andrx's allegations in this action.

9. Biovail objects to Andrx's definitions of the terms "Biovail," "You," and "Your" to the extent that they seek to compel Biovail to respond to these Interrogatories as to persons not under the control of Biovail.

10. Biovail objects to Andrx's definition of the term "Andrx's product" as vague and ambiguous.

11. Biovail objects to Andrx's definition of the term "Biovail Patented Product" as vague, ambiguous, and overly broad.

12. Biovail objects to these Interrogatories to the extent that they request Biovail to identify all evidentiary support, including all the documents supporting Biovail's contentions, on the ground that it is overly broad, unduly burdensome, not reasonably calculated to lead to the discovery of admissible evidence, and premature. Such information is improper at this stage of the action in that it seeks essentially a list of trial exhibits, deposition designations for trial, and a trial witness list. *See, e.g., Steil v. Humana Kansas City, Inc.*, 197 F.R.D. 445, 447 (D. Kan. 2000) (contention interrogatory seeking "every fact and every document" is "overly broad and unduly burdensome").

13. Biovail reserves the right to modify or further supplement these responses upon, among other things, discovery of additional facts and materials, and other developments in this proceeding.

## **RESPONSES**

### **INTERROGATORY NO. 1**

State in detail the complete factual and legal bases for Your allegation that Andrx's product has infringed or will infringe one or more claims of the Patent-In-Suit under 35 U.S.C. § 271, including, but not limited to: (a) identifying each and every claim of the Patent-In-Suit allegedly infringed by the Andrx product; (b) for each element or limitation of such allegedly infringed claim or claims, providing Your proposed construction of each and every term in the claim, and identifying the facts that support your construction of those terms, including, without limitation, portions of the specification and prosecution history of the Patent-In-Suit upon which you rely for your construction; and (c) for each element or limitation of such allegedly infringed claim or claims, explaining in detail how and why Andrx's proposed product allegedly meets that element or limitation.

### **RESPONSE TO INTERROGATORY NO. 1**

In addition to its General Objections, Biovail states that fact and expert discovery is still ongoing, and expert reports are not due until May 16, 2006 pursuant to the current case schedule. Consequently, Biovail reserves the right to amend this response, including the addition of supporting evidence, as that evidence is gathered.

Biovail objects to this Interrogatory to the extent that it calls for expert testimony or information subject to the attorney-client privilege or work product doctrine. Biovail also objects to this Interrogatory as overly broad and unduly burdensome on the ground that it seeks Biovail to set forth a detailed explanation of each and every element of the '791 patent claims. Biovail further objects to this Interrogatory to the extent it seeks Biovail's proposed construction of each and every element of the '791 patent claims. According to the current case schedule, the parties are meant to exchange their respective lists of claim terms that need construction, and their proposed claim construction of those terms on August 15, 2006.

Biovail also objects to this Interrogatory because Andrx has refused to timely provide all documents and samples of Andrx's proposed generic Cardizem LA products, which Biovail requested long ago.

Subject to and without waiving its General and Specific Objections, Biovail contends that Andrx's proposed generic Cardizem LA products infringe Claims 1, 2, 3, and 4 of the '791 patent. The bases for Biovail's contention may be derived or ascertained from the information included in Andrx's Paragraph IV Certification Notices, and in Andrx's ANDA for generic Cardizem LA, ANDA No. 77-686. Moreover, Biovail states that by virtue of Andrx's manufacturing process, beads of Andrx's proposed tableted products will contain an effective amount of a wetting agent in admixture with one or more Diltiazem salts.

#### **INTERROGATORY NO. 2**

For each and every claim identified in response to Interrogatory No. 1, state the dates You contend that the subject matter of the claim was first conceived and first reduced to practice, and state the circumstances allegedly supporting any diligence from conception to reduction to practice, and identify all persons with knowledge of such conception, reduction to practice, and diligence from conception to reduction to practice, and all documents and things relating thereto.

#### **RESPONSE TO INTERROGATORY NO. 2**

In addition to its General Objections, Biovail objects to this Interrogatory as overly broad and unduly burdensome on the ground that it calls for detailed information regarding the first date of conception and reduction to practice for the inventions claimed in the '791 patent. Andrx bears the burden of proving invalidity by clear and convincing evidence, and Andrx has not articulated any contention regarding invalidity of the '791 patent, let alone one that would invoke the dates of conception and reduction to practice of the claimed inventions.

Subject to and without waiving its General and Specific Objections, Biovail states that the inventions of the '791 patent were conceived and reduced to practice at least as of the filing date of the application that led to the '791 patent. Individuals who, as currently apprised, are knowledgeable regarding the conception and reduction to practice of the inventions of the '791 patent are:

Arthur Deboeck  
Galephar P.R. Inc.  
Road 198 Km. 14.7  
#100 Juncos Industrial Park  
Juncos, Puerto Rico 00777-3873

Philippe Baudier  
Galephar P.R. Inc.  
Rue de la Pastorale 26-28  
1080 Brussels, Belgium

### **INTERROGATORY NO. 3**

For each and every claim identified in response to Interrogatory No. 1, explain in detail the circumstances relating to the first synthesis of any embodiment of that claim including, but not limited to, identifying all relevant documents, identifying all individuals participating in said synthesis and identifying the date on which said synthesis occurred.

### **RESPONSE TO INTERROGATORY NO. 3**

In addition to its General Objections, Biovail objects to this Interrogatory as vague and ambiguous to the extent it refers to the first "synthesis" of any embodiment of the '791 patent claims. Biovail further objects to this Interrogatory as overly broad and unduly burdensome on the ground that it calls for detailed information regarding the first synthesis of any embodiment of the '791 patent claims. Andrx bears the burden of proving invalidity by clear and convincing evidence, and Andrx has not articulated any contention regarding invalidity of the '791 patent, let alone one that would invoke the date of the first synthesis of any embodiment of the '791 patent claims.



Subject to and without waiving its General and Specific Objections, individuals who, as currently apprised, are knowledgeable regarding the first synthesis of any embodiment of the '791 patent claims are Arthur Deboeck and Philippe Baudier.

**INTERROGATORY NO. 4**

To the extent you contend that the claim terms "admixture" and "wetting agent" should be construed in any way differently than they were construed by the court in *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 158 F.Supp.2d 1318 (S.D. FL 2000), *aff'd* 239 F.3d 1297 (Fed. Cir. 2001), describe in detail any such differences and the evidence or facts upon which you rely for that difference.

**RESPONSE TO INTERROGATORY NO. 4**

In addition to its General Objections, Biovail objects to this Interrogatory as overly broad, unduly burdensome, and premature on the ground that it seeks Biovail's proposed construction of the '791 patent claims. According to the current case schedule, the parties are meant to exchange their respective lists of claim terms that need construction, and their proposed claim construction of those terms on August 15, 2006.

Subject to and without waiving its General and Specific Objections, Biovail states that the '791 patent claims should be construed in accordance with their plain meaning to one of ordinary skill in the art and in light of the '791 patent's specification and prosecution history.

**INTERROGATORY NO. 5**

For each and every Biovail Patented Product, identify the person with the most knowledge of research and development, of manufacturing, of marketing, of sales, of distribution, and of advertising or promotion.

**RESPONSE TO INTERROGATORY NO. 5**

In addition to its General Objections, Biovail objects to this Interrogatory as vague, ambiguous, overly broad, and unduly burdensome on the ground that it seeks

the identification of persons most knowledgeable as to broad, undefined subject areas.

Biovail further objects to this Interrogatory to the extent it calls for the identification of persons that are not relevant to any of Biovail's claims and defenses, or any articulated defense of Andrx.

Subject to and without waiving its General and Specific Objections, Biovail identifies the following individuals who, as currently apprised, are knowledgeable regarding the research and development, and manufacturing of Cardizem® LA:

Wayne Kreppner  
Biovail Corporation  
2488 Dunwin Drive  
Mississauga, ON L5L 1J9

Paul Regus Maes  
Maes Pharmaconsult SPRL  
21 Avenue Georges Pompidou  
F-69003 Lyon, France

Biovail also identifies the following individual who, as currently apprised, is knowledgeable regarding the marketing, sales, distribution, advertising, and promotion of Cardizem® LA:

Rick Keefer  
Biovail Pharmaceutical Inc.  
700 Route 202/206 North  
Bridgewater, NJ 08807

#### **INTERROGATORY NO. 6**

To the extent You contend that there are secondary considerations or objective indicia of non-obviousness relating to the claimed subject matter of the Patent-In-Suit, describe in detail those considerations and indicia, identify each person with knowledge of such facts, and identify each document referring or relating to such facts.

#### **RESPONSE TO INTERROGATORY NO. 6**

In addition to its General Objections, Biovail objects to this Interrogatory as overly broad and unduly burdensome on the ground that it calls for detailed information regarding secondary considerations of nonobviousness. Andrx bears the

burden of proving by clear and convincing evidence that the inventions claimed in the '791 patent would have been obvious. Biovail contends that a *prima facie* case has not and cannot be established by Andrx. It is improper for Andrx to demand that Biovail set forth its contentions demonstrating secondary considerations of nonobviousness with respect to the '791 patent when Andrx has not articulated a *prima facie* obviousness invalidity defense.

#### **INTERROGATORY NO. 7**

For each and every Biovail Patented Product, describe in detail the first sale, offer for sale, commercialization, public disclosure, public use, and experimental use of each product, and all documents or things relating thereto.

#### **RESPONSE TO INTERROGATORY NO. 7**

In addition to its General Objections, Biovail objects to this Interrogatory as overly broad and unduly burdensome on the ground that it calls for detailed information regarding the first sale, offer for sale, commercialization, public disclosure, public use, and experimental use of Cardizem® LA. Andrx bears the burden of proving invalidity by clear and convincing evidence, and Andrx has not articulated any contention regarding invalidity of the '791 patent, let alone one that would invoke the dates of sale, offer for sale, or uses of Cardizem® LA.

Subject to and without waiving its General and Specific Objections, Biovail states that on February 6, 2003, the FDA approved its NDA to market Cardizem® LA in the United States.

**INTERROGATORY NO. 8**

For each and every Biovail Patented Product, describe in detail the step or steps in the manufacturing processes by which the product becomes a "galenical composition of one or more pharmaceutically acceptable salts of diltiazem which comprises beads containing an effective amount of one or more of the diltiazem salts and an effective amount of a wetting agent in admixture with the one or more diltiazem salts," and where the "beads [are] coated with a microporous membrane comprising at least a water-soluble or water-dispersible polymer or copolymer, and a water-, acid, and base insoluble polymer and a pharmaceutically-acceptable adjuvant" as You propose to construe that claim language in the Patent-In-Suit and identify the person with the most knowledge of the step or steps in the manufacturing processes.

**RESPONSE TO INTERROGATORY NO. 8**

In addition to its General Objections, Biovail objects to this Interrogatory as vague, ambiguous, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks detailed information regarding the manufacture of Biovail's Cardizem® LA products.

Subject to and without waiving its General and Specific Objections, Biovail states that information regarding the manufacture of Cardizem® LA may be derived or ascertained from the "Chemistry, Manufacturing and Controls" section of Biovail's NDA for Cardizem® LA, NDA No. 21-392. Individuals who, as currently apprised, are knowledgeable regarding the manufacturing of Cardizem® LA are Wayne Kreppner and Paul Maes.

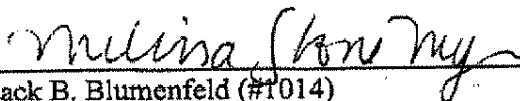
**INTERROGATORY NO. 9**

Identify each and every person who provided information that was included in, or considered for inclusion in, Your responses to these interrogatories or Andrx's First Request For The Production of Documents and Things To Biovail, and state whether the files (including but not limited to memoranda and/or correspondence files in hardcopy or electronic form) for each such person were fully searched for information and documents responsive to these interrogatories and those requests for documents and things.

**RESPONSE TO INTERROGATORY NO. 9**

In addition to its General Objections, Biovail objects to this Interrogatory to the extent it seeks information subject to the attorney-client privilege or work product doctrine. Biovail further objects to this Interrogatory as irrelevant and outside the scope of discovery allowed by Rules 26(b)(1) and 33(c) of the Federal Rules of Civil Procedure.

MORRIS, NICHOLS, ARSHT & TUNNELL

  
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December 23, 2005

VERIFICATION

I, Dina Khair declare under penalty of perjury under the laws of the United States of America that I have been authorized to sign this Verification on behalf of Plaintiff Biovail; that I have read the foregoing Biovail's Responses to Defendant Andrx's First Set of Interrogatories; and to the best of my knowledge and belief the facts indicated therein are true and correct.

Dec 23, 2005

Attairs

**CERTIFICATE OF SERVICE**

I, Melissa Stone Myers, hereby certify that copies of the foregoing were caused to be served this 23rd day of December, 2005 upon the following in the manner indicated:

**BY HAND**

William J. Cattie  
Rawle & Henderson, LLP  
300 Delaware Avenue  
Suite 1015  
P.O. Box 588  
Wilmington, DE 19899

**BY FEDERAL EXPRESS**

Martin P. Endres  
Hedman & Costigan, P.C.  
1185 Avenue of the Americas  
New York, NY 10036

Steven Maddox  
Foley & Lardner, LLP  
3000 K Street, NW  
Washington, DC 20007



Melissa Stone Myers (#3985)  
mmyers@mnat.com

# **EXHIBIT B**



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL  
a corporation of Barbados,

Plaintiff,

v.

ANDRX PHARMACEUTICALS, LLC and  
ANDRX CORPORATION,

Defendants.

C.A. No. 05-586 (KAJ)

**BIOVAIL'S RESPONSES TO DEFENDANT ANDRX'S FIRST SET OF  
REQUESTS FOR THE PRODUCTION OF DOCUMENTS AND THINGS**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and  
Local Civil Rules 5.4 and 26.1 of the United States District Court for the District of  
Delaware, Plaintiff Biovail Laboratories International SRL ("Biovail") hereby submits its  
responses and objections to Defendants Andrx Pharmaceuticals, LLC's and Andrx  
Corporation's (collectively "Andrx") First Request for the Production of Documents and  
Things to Biovail (the "Requests").

### **GENERAL OBJECTIONS**

Biovail makes the following General Objections to the Requests, which apply to each individual Request, and shall have the same force and effect as if fully set forth in response to each individual Request:

1. Biovail objects to the Requests to the extent that they seek documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Nothing contained in Biovail's responses is intended to be, or in any way shall be deemed to be, a waiver of any such applicable privilege or immunity.
2. Biovail objects to the Requests to the extent that they seek documents that are not within the possession, custody or control of Biovail.
3. Biovail objects to the Requests to the extent that they purport to impose obligations on Biovail that exceed its obligations under the Federal Rules of Civil Procedure and the Local Civil Rules of the United States District Court for the District of Delaware.
4. Biovail objects to the Requests to the extent that they are vague, ambiguous, overly broad, unduly burdensome, not reasonably calculated to lead to the discovery of admissible evidence, seek documents that are irrelevant to any claim or defense in this action and would require Biovail to conduct an unreasonable and unduly burdensome search for responsive documents. Subject to its objections, Biovail will conduct a reasonable search for documents responsive to the Requests.
5. Biovail objects to the Requests to the extent that they call for the production of confidential or proprietary information. Subject to its objections, Biovail

will produce responsive confidential documents pursuant to entry of an appropriate protective order by the Court.

6. Biovail objects to the Requests to the extent that they call for the production of confidential information of any third party that is in the possession of Biovail pursuant to confidentiality and non-disclosure restrictions imposed by contract or applicable law.

7. Biovail's U.S. Patent No. 5,529,791 (the "791 patent") is directed to formulations of extended release diltiazem compositions. Accordingly, unless otherwise indicated in Biovail's responses, Biovail objects to each Request insofar as it seeks documents beyond those relating to the formulation of its extended release diltiazem compositions. Any such request is overly broad, unduly burdensome and calls for the production of documents and things that are neither relevant to any issue in this action nor reasonably calculated to lead to the discovery of admissible evidence.

8. Biovail objects to the Requests to the extent that they call for documents created after June 22, 2005, the date of the first Notice pursuant to Title I of the Drug Price Competition and Patent Term Restoration Act of 1983, Section 505(j)(2)(B)(i) and (ii) concerning generic Cardizem LA, as overly broad, unduly burdensome, not reasonably calculated to lead to the discovery of admissible evidence and seeking information that is irrelevant, privileged and subject to the work product doctrine.

9. Biovail objects to the Requests to the extent that they call for documents relating to products offered for sale or sold outside of the United States.

10. Biovail objects to Andrx's definitions of the terms "Biovail," "You," and "Your" to the extent they seek to compel Biovail to respond to these Requests as to persons not under the control of Biovail.

11. Biovail objects to Andrx's definition of the term "Andrx's product" as vague and ambiguous.

12. Biovail objects to Andrx's definition of the term "Biovail Patented Product" to the extent that it is vague, ambiguous and overly broad.

13. Biovail objects to Andrx's Instruction No. 23 on the grounds that it is vague, ambiguous, and meaningless as it refers to the identification of documents in lieu of "answering the information."

14. No objection, limitation, or response, or lack thereof made herein, shall be an admission by Biovail as to (a) the truth of any of the statements made in the Requests, or (b) the existence or non-existence of documents responsive to the Requests. By stating in its responses that it will produce documents, Biovail does not waive its objections or represent that any such document or thing actually exists, but rather that Biovail will conduct a reasonable search and attempt to ascertain whether documents and things responsive to the Requests in fact exist.

15. To the extent that the Requests call for documents and *things* that were provided to Andrx in Biovail Corp. Int'l v. Andrx Pharms., Inc., Civil Action No. 98-Civ-7096 (S.D. Fla.) (the "Tiazac® litigation"), Biovail objects to producing a duplicative set of such documents and things.

16. These responses and the objections and limitations contained herein are subject to and without waiver of (a) the right to make additional or

supplemental objections to these or other document requests, and (b) the right to revise, correct, amend, or modify these responses.

### **RESPONSES AND SPECIFIC OBJECTIONS**

#### **REQUEST NO. 1**

All documents and things that You have produced in any case involving the Patent-In-Suit.

#### **RESPONSE TO REQUEST NO. 1**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence. Biovail also objects on the grounds set forth in General Objection No. 15.

#### **REQUEST NO. 2**

All documents or things You have submitted to any court, decision-maker or party in any case, conflict, opposition, interference, nullity or other proceeding involving the Patent-In-Suit.

#### **RESPONSE TO REQUEST NO. 2**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence. Biovail also objects on the grounds set forth in General Objection No. 15.

**REQUEST NO. 3**

All documents and things that You have produced in any case, conflict, opposition, interference, nullity or other proceeding involving a United States or foreign patent or United States or foreign patent application that refers or relates to subject matter disclosed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 3**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence. Biovail also objects on the grounds set forth in General Objection No. 15.

**REQUEST NO. 4**

All documents and things that You have submitted to any foreign or United States court, decision-maker or party in any case, conflict, opposition, nullity or infringement proceeding involving a United States or foreign patent or United States or foreign patent application that refers or relates to subject matter disclosed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 4**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence. Biovail also objects on the grounds set forth in General Objection No. 15.

**REQUEST NO. 5**

All documents referring or relating to any PCT application or foreign patents and foreign patent applications that correspond to the subject matter disclosed in the Patent-In-Suit, including, but not limited to, any PCT application, or foreign patent or foreign patent application that claims priority to the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 5**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

Subject to these objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 6**

All documents and things relating to the invention, design, conception, development, and reduction to practice of each of the alleged inventions that are the subject matter disclosed and claimed in the Patent-In-Suit, including but not limited to inventor notebooks, invention disclosures, notes, memoranda, correspondence, records or meetings, drawings, schematics, photographs, models, and working embodiments.

**RESPONSE TO REQUEST NO. 6**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

Subject to these objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 7**

All documents and things referring to, relating to, or evidencing the dates of invention, design, conception, development, and reduction to practice of each of the alleged inventions that are the subject matter disclosed and claimed in the Patent-In-Suit, including but not limited to inventor notebooks, invention disclosures, notes, memoranda, correspondence, records or meetings, drawings, schematics, photographs, models, and working embodiments.

**RESPONSE TO REQUEST NO. 7**

Biovail objects to this Request on the grounds that it is duplicative of Request No. 6 and in response Biovail incorporates by reference its response to that Request.

**REQUEST NO. 8**

All documents referring or relating to the assertion or threatened assertion of the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 8**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

Subject to these objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 9**

All documents and things referring or relating to the inventorship of the alleged inventions that are the subject matter of the Patent-In-Suit, including but not limited to documents that refer to or relate to the contribution of any individuals to said alleged inventions or any discussion or decision regarding the naming of such individuals as inventors.



**RESPONSE TO REQUEST NO. 9**

Subject to its General Objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 10**

Any and all documents and things used, consulted, considered, or relied on by the named inventors of the Patent-In-Suit during the development, testing, or analysis of the subject matter disclosed and claimed in the Patent-In-Suit, including but not limited to inventor notebooks, invention disclosures, notes, memoranda, correspondence, records or meetings, drawings, schematics, photographs, models, and working embodiments.

**RESPONSE TO REQUEST NO. 10**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

Subject to these objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 11**

All documents that refer or relate to the research and development of any Biovail Patented Product.

**RESPONSE TO REQUEST NO. 11**

To the extent that this Request calls for documents beyond those relating to the formulation of its Cardizem® LA products, Biovail objects on the grounds set forth

in General Objection No. 7. Biovail further objects to this Request as overly broad and unduly burdensome.

**REQUEST NO. 12**

All documents that refer or relate to any formulation of the Biovail Patented Product.

**RESPONSE TO REQUEST NO. 12**

Subject to its General Objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 13**

All documents that refer or relate to the testing of any Biovail Patented Product, including documents sufficient to show test results, or any other documents.

**RESPONSE TO REQUEST NO. 13**

To the extent that this Request calls for documents beyond those relating to the formulation of its Cardizem® LA products, Biovail objects on the grounds set forth in General Objection No. 7. Biovail further objects to this Request as overly broad and unduly burdensome insofar as it relates to any type of testing without limitation.

**REQUEST NO. 14**

All documents that refer or relate to the marketing of any Biovail Patented Product.

**RESPONSE TO REQUEST NO. 14**

In addition to its General Objections, Biovail objects to this Request as overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 15**

All documents that refer or relate to the advertising of any Biovail Patented Product.

**RESPONSE TO REQUEST NO. 15**

In addition to its General Objections, Biovail objects to this Request as overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 16**

All documents that refer or relate to the distribution of any Biovail Patented Product.

**RESPONSE TO REQUEST NO. 16**

In addition to its General Objections, Biovail objects to this Request as overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 17**

All documents that refer or relate to any clinical studies performed by You or on Your behalf for any Biovail Patented Product.

**RESPONSE TO REQUEST NO. 17**

To the extent that this Request calls for documents beyond those relating to the formulation of its Cardizem® LA products, Biovail objects on the grounds set forth in General Objection No. 7. Biovail further objects to this Request as overly broad and unduly burdensome.

**REQUEST NO. 18**

For each Biovail Patented Product, documents sufficient to show the first or earliest date for which the product was sold or offered for sale.

**RESPONSE TO REQUEST NO. 18**

Subject to its General Objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 19**

For each Biovail Patented Product, all documents that refer or relate to efforts to obtain regulatory approval in the United States and in any foreign country.

**RESPONSE TO REQUEST NO. 19**

To the extent that this Request calls for documents beyond those relating to the formulation of its Cardizem® LA products, Biovail objects on the grounds set forth in General Objection No. 7. Biovail further objects to this Request as vague, ambiguous, overly broad and unduly burdensome.

**REQUEST NO. 20**

For each Biovail Patented Product, documents sufficient to show quarterly and annual gross revenue, gross profit, and net profit from sales for the past five (5) years.

**RESPONSE TO REQUEST NO. 20**

In addition to its General Objections, Biovail objects to this Request as overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 21**

For each Biovail Patented Product, all documents sufficient to show wholesale and retail prices charged for the product for the past five (5) years.

**RESPONSE TO REQUEST NO. 21**

In addition to its General Objections, Biovail objects to this Request as overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 22**

For each Biovail Patented Product, documents sufficient to show quarterly and annual gross revenue, gross profit, and net profit from projected sales through 2010.

**RESPONSE TO REQUEST NO. 22**

In addition to its General Objections, Biovail objects to this Request as overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 23**

For each Biovail Patented Product, all projections of wholesale and retail prices through 2010.

**RESPONSE TO REQUEST NO. 23**

In addition to its General Objections, Biovail objects to this Request as overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 24**

All documents that refer or relate to the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 24**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome.

**REQUEST NO. 25**

All patents that issued from any of the applications that led to the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 25**

In addition to its General Objections, Biovail objects to this Request to the extent it seeks to compel Biovail to make a search or analysis of publicly available documents or records.

**REQUEST NO. 26**

All documents that refer or relate to Andrx or any of its parents, subsidiaries or affiliated companies.

**RESPONSE TO REQUEST NO. 26**

In addition to its General Objections, Biovail objects to this Request as overly broad and unduly burdensome as it calls for all documents that refer or relate to Andrx or any of its parents, subsidiaries or affiliated companies without limitation as to time or subject matter.

**REQUEST NO. 27**

All licenses referring or relating to the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 27**

Subject to its General Objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 28**

All agreements, other than licenses, that refer or relate to the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 28**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome.

**REQUEST NO. 29**

All documents that refer or relate to Galephar, P.R.

**RESPONSE TO REQUEST NO. 29**

In addition to its General Objections, Biovail objects to this Request as overly broad and unduly burdensome as it calls for all documents that refer or relate to Galephar, P.R. without limitation as to time or subject matter.

**REQUEST NO. 30**

All documents and things that refer or relate to any due diligence in the licensing of the '791 patent.

**RESPONSE TO REQUEST NO. 30**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 31**

Entry into Biovail's facility or facilities used in the formulation and manufacturing of each Biovail Patented Product for the purpose of inspection and videotaping of the formulation and manufacturing processes.

**RESPONSE TO REQUEST NO. 31**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it is irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 32**

Each and every document upon which You rely to support Your construction of any claim in the Patent-In-Suit for which You assert infringement against Andrx,

**RESPONSE TO REQUEST NO. 32**

In addition to its General Objections, Biovail objects to this Request to the extent it seeks to compel Biovail to make a search or analysis of publicly available documents or records.

Subject to these objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 33**

For each claim that You identified in response to Request No. 32, each and every document which refutes Your construction of any claim in the Patent-In-Suit for which You assert infringement against Andrx.

**RESPONSE TO REQUEST NO. 33**

In addition to its General Objections, Biovail objects to this Requests as ambiguous, vague, incomprehensible and incomplete as Request No. 32 does not require Biovail to identify any claim.

Subject to these objections, Biovail is unaware of any documents that refute its construction of the '791 patent claims.



**REQUEST NO. 34**

If You contend that the claimed inventions of the Patent-In-Suit are nonobvious in light of commercial success, unexpected results, or any other secondary considerations, produce all documents referring or relating to commercial success, unexpected results, or any other secondary considerations, or any other document that supports or refutes Your contention.

**RESPONSE TO REQUEST NO. 34**

In addition to its General Objections, Biovail objects to this request as premature and reserves the right to supplement its response if Andrx fully articulates and supports a *prima facie* obviousness position in response to a Biovail interrogatory requesting such information.

**REQUEST NO. 35**

One Hundred Samples of each Biovail Patented Product.

**RESPONSE TO REQUEST NO. 35**

Subject to its General Objections, Biovail will produce samples of its Cardizem® LA products.

**REQUEST NO. 36**

All documents concerning the subject matter disclosed and/or claimed in the Patent-In Suit.

**RESPONSE TO REQUEST NO. 36**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 37**

All documents concerning any evaluation or study of the subject matter disclosed and/or claimed in the Patent-In-Suit by or on behalf of Biovail, including, but not limited to, opinions concerning infringement, non-infringement, validity, invalidity, enforceability, unenforceability, and inequitable conduct.

**RESPONSE TO REQUEST NO. 37**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

Subject to these objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 38**

All documents dated or published prior to September 23, 1994 which depict or relate to any aspect or feature of the subject matter disclosed and/or claimed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 38**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request to the extent it seeks to compel Biovail to make a search or analysis of publicly available documents or records.

**REQUEST NO. 39**

All documents concerning any claim or contention made by any person challenging the validity of any claim of the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 39**

Subject to its General Objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 40**

All documents concerning any claim or contention made by any person or entity challenging the enforceability of the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 40**

Subject to its General Objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 41**

All documents concerning any claim or contention made by any person or entity challenging infringement of the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 41**

Subject to its General Objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 42**

All documents concerning the first use of any kind of the subject matter disclosed and/or claimed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 42**

Biovail objects to this Request on the grounds that it is duplicative of Request No. 6 and in response Biovail incorporates by reference its response to that Request.

**REQUEST NO. 43**

All documents concerning the first experimental use of any kind of the subject matter disclosed and/or claimed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 43**

Biovail objects to this Request on the grounds that it is duplicative of Request No. 6 and in response Biovail incorporates by reference its response to that Request.

**REQUEST NO. 44**

All documents and things relating or referring to the first disclosure of each invention disclosed or claimed in the Patent-In-Suit to any person or entity.

**RESPONSE TO REQUEST NO. 44**

Biovail objects to this Request on the grounds that it is duplicative of Request No. 6 and in response Biovail incorporates by reference its response to that Request.

**REQUEST NO. 45**

All documents concerning any communication with the FDA, state pharmacy boards, and/or any other third party regarding Andrx.

**RESPONSE TO REQUEST NO. 45**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 46**

All documents constituting, referring, or relating to any New Drug Application ("NDA") submitted to the FDA concerning the use of any Biovail Patented Product for any indication.

**RESPONSE TO REQUEST NO. 46**

To the extent that this Request calls for documents beyond those relating to the formulation of its Cardizem® LA products, Biovail objects on the grounds set forth in General Objection No. 7. Biovail further objects to this Request as overly broad and unduly burdensome.

**REQUEST NO. 47**

All documents referring or relating to any product or device known to be equivalent to any Biovail Patented Product.

**RESPONSE TO REQUEST NO. 47**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 48**

All documents and things referring or relating to any foreign or domestic product or device known to be competitive with any Biovail Patented Product.

**RESPONSE TO REQUEST NO. 48**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense

in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 49**

Documents and things sufficient to show the current organizational structure of Biovail, including, without limitation, documents sufficient to identify Biovail's officers, directors and managerial employees and their respective duties and responsibilities including, without limitations, documents sufficient to identify every person who has knowledge concerning Biovail or Biovail's products, who has ever made a statement concerning Biovail or Biovail's products, and who has ever received or responded to comments, statements, questions or inquiries concerning Biovail or Biovail's products.

**RESPONSE TO REQUEST NO. 49**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome.

Subject to these objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 50**

Any and all documents, data compilations, and tangible things in the possession, custody, or control of Biovail that are relevant to facts in the pleadings, including, but not limited to all documents identified in, referred to, and/or used in the preparation of the Plaintiff's Complaint and/or any other Pleading.

**RESPONSE TO REQUEST NO. 50**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 51**

Any and all documents referring or relating to any United States or foreign patent or patent application where Arthur M. Deboeck is listed as a named inventor and where the claimed invention relates to the subject matter disclosed in the Patent-In-Suit, including but not limited to inventor note books, invention disclosures, notes, memoranda, correspondence, records or meetings, drawings, schematics, photographs, models, and working embodiments.

**RESPONSE TO REQUEST NO. 51**

To the extent that this Request calls for documents beyond those relating to the formulation of its Cardizem® LA products, Biovail objects on the grounds set forth in General Objection No. 7. Biovail further objects to this Request as vague, ambiguous, overly broad and unduly burdensome.

**REQUEST NO. 52**

Any and all documents referring or relating to any United States or foreign patent or patent application where Phillippe R. Baudier is listed as a named inventor and where the claimed invention relates to the subject matter disclosed in the Patent-In-Suit, including but not limited to inventor note books, invention disclosures, notes, memoranda, correspondence, records or meetings, drawings, schematics, photographs, models, and working embodiments.

**RESPONSE TO REQUEST NO. 52**

To the extent that this Request calls for documents beyond those relating to the formulation of its Cardizem® LA products, Biovail objects on the grounds set forth in General Objection No. 7. Biovail further objects to this Request as vague, ambiguous, overly broad and unduly burdensome.

**REQUEST NO. 53**

Documents, including correspondence, sufficient to identify all outside counsel, agents, or representatives who have assisted in the preparation, prosecution, licensing or cross-licensing, or enforcement of any United States or foreign patent or patent application where the claimed invention relates to the subject matter disclosed and/or claimed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 53**

In addition to its General Objections, Biovail objects to this Request to the extent it seeks to compel Biovail to make a search or analysis of publicly available documents or records.

Subject to these objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 54**

Any and all documents referring and relating to the research and development which led to the alleged subject matter claimed in the Patent-In-Suit or any United States or foreign patent and/or United States or foreign application filed by or on behalf [sic] Biovail which relate to the subject matter disclosed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 54**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

Subject to these objections, Biovail will produce non-privileged, non-work product documents responsive to this Request regarding the invention of the '791 patent to the extent that they were not already provided to Andrx in the Tiazac® litigation.



**REQUEST NO. 55**

Documents referring or relating to any formulation of any compound or device that relates in any way to the subject matter disclosed and/or claimed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 55**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 56**

To the extent not produced in response to the foregoing requests for production, all documents demonstrating, evidencing, establishing, supporting, or refuting Your contentions in this litigation.

**RESPONSE TO REQUEST NO. 56**

Subject to its General Objections, Biovail will produce non-privileged, non-work product documents demonstrating, evidencing, establishing, and supporting its contentions in this action to the extent that they were not already provided to Andrx in the Tiazac® litigation. Biovail is unaware of any documents that refute its contentions in this action.

**REQUEST NO. 57**

To the extent not otherwise produced in response to the Requests herein, any and all documents and things submitted in, produced in, or resulting from any litigation, arbitration, interference, or opposition proceeding between Biovail and any other person or entity relating or referring to the alleged inventions disclosed and claimed in the Patent-In-Suit, including but not limited to pleadings, affidavits, memoranda of law, opinions, orders, decisions, transcripts, appeal papers, correspondence, licenses, and agreements.

**RESPONSE TO REQUEST NO. 57**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence. Biovail also objects on the grounds set forth in General Objection No. 15.

**REQUEST NO. 58**

All document describing Biovail's procedures, policies, practices and facilities for generating, maintaining and destroying business records, including but not limited to any and all documents and things relating or referring to the Patent-In-Suit that have been destroyed or transferred to the possession of another person not subject to Biovail's direction or control.

**RESPONSE TO REQUEST NO. 58**

Subject to its General Objections, Biovail will produce non-privileged, non-work product documents responsive to this Request to the extent that they were not already provided to Andrx in the Tiazac® litigation.

**REQUEST NO. 59**

To the extent not otherwise produced in response to the Requests herein, any and all documents and things relating or referring to communications between Biovail and any third party referring or relating to the Patent-In-Suit, and/or enforcement of the Patent-In-Suit, including but not limited to any prospectus, news release, solicitation or brochure.

**RESPONSE TO REQUEST NO. 59**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence.

**REQUEST NO. 60**

All documents and things that You have produced in any case, conflict, opposition, interference, nullity or other proceeding involving Rhoxalpharma or any related entity and a United States or foreign patent, including but not limited to Canadian patents, or United States or foreign patent application that refers or relates to subject matter disclosed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 60**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence. Biovail also objects on the grounds set forth in General Objection No. 15.

**REQUEST NO. 61**

All documents and things that You have produced in any case, conflict, opposition, interference, nullity or other proceeding involving Apotex or any related entity and a United States or foreign patent or United States or foreign patent application that refers or relates to subject matter disclosed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 61**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence. Biovail also objects on the grounds set forth in General Objection No. 15.

**REQUEST NO. 62**

All documents and things that You have produced in any case, conflict, opposition, interference, nullity or other proceeding involving Torpharm or any related entity and a United States or foreign patent or United States or foreign patent application that refers or relates to subject matter disclosed in the Patent-In-Suit.

**RESPONSE TO REQUEST NO. 62**

In addition to its General Objections, Biovail objects to this Request as vague, ambiguous, overly broad and unduly burdensome. Biovail further objects to this Request on the grounds that it seeks documents that are irrelevant to any claim or defense in this action and is not reasonably calculated to lead to the discovery of admissible evidence. Biovail also objects on the grounds set forth in General Objection No. 15.

MORRIS, NICHOLS, ARSHT & TUNNELL

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December 1, 2005

# **EXHIBIT C**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

RECEIVED  
JAN 23 2006  
BY: \_\_\_\_\_

BIOVAIL LABORATORIES INTERNATIONAL SRL  
a corporation of Barbados,

Plaintiff,

v.

ANDRX PHARMACEUTICALS, LLC and  
ANDRX CORPORATION,

Defendants.

C.A. No. 05-586 (KAJ)

**BIOVAIL'S SUPPLEMENTAL RESPONSES TO  
DEFENDANT ANDRX'S INTERROGATORY NOS. 1 AND 4**

Pursuant to Rule 33 of the Federal Rules of Civil Procedure and the Local Civil Rules of the United States District Court for the District of Delaware, Plaintiff Biovail Laboratories International SRL ("Biovail"), submits the following supplemental responses and objections to Defendants, Andrx Pharmaceuticals, LLC and Andrx Corporation (collectively "Andrx") Interrogatory Nos. 1 and 4.

### **GENERAL OBJECTIONS**

Biovail incorporates by reference the General Objections set forth in its Responses to Defendant Andrx's First Set of Interrogatories dated December 23, 2005. These General Objections are applicable to, and are incorporated in each supplemental response.

### **SUPPLEMENTAL RESPONSES**

#### **INTERROGATORY NO. 1**

State in detail the complete factual and legal bases for Your allegation that Andrx's product has infringed or will infringe one or more claims of the Patent-In-Suit under 35 U.S.C. § 271, including, but not limited to: (a) identifying each and every claim of the Patent-In-Suit allegedly infringed by the Andrx product; (b) for each element or limitation of such allegedly infringed claim or claims, providing Your proposed construction of each and every term in the claim, and identifying the facts that support your construction of those terms, including, without limitation, portions of the specification and prosecution history of the Patent-In-Suit upon which you rely for your construction; and (c) for each element or limitation of such allegedly infringed claim or claims, explaining in detail how and why Andrx's proposed product allegedly meets that element or limitation.

#### **SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 1**

In addition to its General Objections, Biovail states that fact and expert discovery is still ongoing, and expert reports are not due until May 16, 2006 pursuant to the current case schedule. Consequently, Biovail reserves the right to amend or further supplement this response, including the addition of supporting evidence, as that evidence is gathered.

Biovail objects to this Interrogatory to the extent that it calls for expert testimony or information subject to the attorney-client privilege or work product doctrine. Biovail also objects to this Interrogatory as overly broad and unduly burdensome on the ground that it seeks Biovail to set forth a detailed explanation of each and every element of the '791 patent claims. Biovail further objects to this Interrogatory to the extent it seeks Biovail's proposed construction of each and every element of the '791 patent claims. According to the current case schedule, the

parties are meant to exchange their respective lists of claim terms that need construction, and their proposed claim construction of those terms on August 15, 2006.

Biovail also objects to this Interrogatory because Andrx has refused to timely provide all documents and samples of Andrx's proposed generic Cardizem LA products, which Biovail requested long ago.

Subject to and without waiving its General and Specific Objections, based on the discovery to date, Biovail contends that Andrx's proposed generic Cardizem LA products infringe Claims 1-4 of the '791 patent.

Claim 1 of the '791 patent is directed to extended-release galenical compositions comprising beads containing the active ingredient Diltiazem, a wetting agent in admixture with the Diltiazem, and the beads are coated with a microporous membrane. The microporous membrane comprises at least a water-soluble or water-dispersible polymer or copolymer, and a water-, acid- and base- insoluble polymer, and an adjuvant. The adjuvant may be a plastifying agent, pigment, lubricant, or antifoam agent. (See '791 patent, col. 3, lines 8-10.) The wetting agent may be any of the following ingredients: sugars, C<sub>12</sub>-C<sub>20</sub> fatty acid esters of sucrose or xylose, glycerides of sucrose, fatty acid esters of polyoxyethylene, esters of fatty alcohols and polyoxyethylene, esters of sorbitan, esters of polyoxyethylene sorbitan, alcohol-polyglycide esters, glyceride-polyglycides, lecithins, and combinations thereof.

Claims 2 through 4 of the '791 patent are dependant on Claim 1, and include further requirements. Claim 2 provides that the wetting agent is a sugar. Claim 3 provides that the wetting agent is about 8% by weight of the composition, and Claim 4 provides that the wetting agent is sucrose stearate, and that the microporous membrane comprises hydroxypropylmethyl-cellulose as the water-soluble or water-dispersible polymer or copolymer, and an acrylic polymer as the water-, acid- and base- insoluble polymer.



The '791 patent claims should be construed in accordance with their plain meaning to one of ordinary skill in the art and in light of the '791 patent's specification and prosecution history. The Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, reaffirmed that claims are construed as a person of ordinary skill in the art would have understood at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-14 (Fed. Cir. 2005). The *Phillips* Court made plain that a patent's claims, specification, and prosecution file history are sources of information in a claim construction analysis. *Phillips*, 415 F.3d 1303, 1312-1317.

Andrx's proposed generic Cardizem LA products have beads containing Diltiazem, a wetting agent, and a microporous membrane as recited in Claims 1-4 of the '791 patent. As shown in Andrx's Components and Composition Statements, wetting agents include, for example, sugar spheres and esters of polyoxyethylene sorbitan (i.e., Polysorbate 80). The microporous membrane in Andrx's beads include a water-soluble or water-dispersible polymer or copolymer (Hydromellose 2910); a water-, acid- and base-insoluble polymer (Eudragit NE 30D); and an additional adjuvant, e.g., magnesium stearate and talc. In Andrx's manufacturing process, its beads are blended with other adjuvants, and then are compressed into tablets. By virtue of the manufacturing process, beads of Andrx's proposed tableted products will contain a wetting agent in admixture with Diltiazem, as recited by Claims 1-4 of the '791 patent, and as the term "admixture" is construed according to the principles enunciated in the recent *Phillips* decision. Andrx's proposed tableted products thus infringe those claims.

Andrx's proposed tableted products infringe Claim 1 of the '791 patent because they have beads containing Diltiazem, a wetting agent (e.g., sugar spheres and esters of polyoxyethylene sorbitan) in admixture with the Diltiazem, and a microporous membrane including a water-soluble or water-dispersible polymer or copolymer (Hydromellose 2910), and

a water-, acid- and base-insoluble polymer (Eudragit NE 30D); and an additional adjuvant, e.g., magnesium stearate and talc.

Andrx's proposed tableted products infringe Claim 2 of the '791 patent because they include sugar (e.g., sugar spheres) as a wetting agent.

Andrx's tableted products infringe Claim 3 of the '791 patent because the wetting agent in its products (e.g., sugar spheres and esters of polyoxyethylene sorbitan) is about 8% by weight of its product compositions.

Andrx's tableted products infringe Claim 4 of the '791 patent because they include a wetting agent equivalent to sucrose stearate (e.g., sugar spheres and esters of polyoxyethylene sorbitan), and the water-soluble or water-dispersible polymer or copolymer is hydroxypropylmethyl-cellulose (Hypromellose 2910), and the water-, acid- and base- insoluble polymer is an acrylic polymer (Eudragit NE 30D).

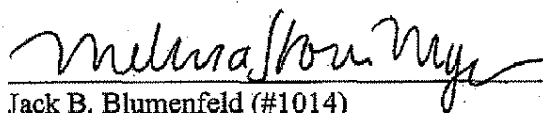
**INTERROGATORY NO. 4**

To the extent you contend that the claim terms "admixture" and "wetting agent" should be construed in any way differently than they were construed by the court in *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 158 F.Supp.2d 1318 (S.D. Fl. 2000), *aff'd* 239 F.3d 1297 (Fed. Cir. 2001), describe in detail any such differences and the evidence or facts upon which you rely for that difference.

**RESPONSE TO INTERROGATORY NO. 4**

In addition to its General Objections, Biovail objects to this Interrogatory as overly broad, unduly burdensome, and premature. Subject to and without waiving its General and Specific Objections, Biovail incorporates by reference its Supplemental Response to Interrogatory No. 1.

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January 20, 2006

**CERTIFICATE OF SERVICE**

I, Melissa Stone Myers, hereby certify that copies of the foregoing were caused to be served this 20<sup>th</sup> day of January, 2006 upon the following in the manner indicated:

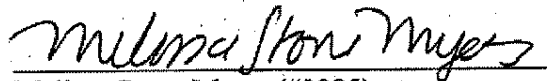
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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL, )

Plaintiff, )

v. )

ANDRX PHARMACEUTICALS, LLC and )  
ANDRX CORPORATION, )

Defendants. )

C.A. No. 05-586 (KAJ)

**NOTICE OF SERVICE**

The undersigned hereby certifies that copies of *Biovail's Supplemental Responses to Defendant Andrx's Interrogatories Nos. 1 and 4* were caused to be served on January 20, 2006 upon the following in the manner indicated:

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I, Melissa Stone Myers, hereby certify that on January 20, 2006, I caused to be electronically filed *Notice of Service of Biovail's Supplemental Responses to Defendant Andrx's Interrogatories Nos. 1 and 4* with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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